

### **REMARKS**

Claims 1, 2, 4-9, 11-23, and 25-30 are pending in the application for the Examiner's review and consideration. In response to Examiner's objection to claim 1, Applicant includes a marked-up copy of Claim 1 in Appendix A, attached hereto, showing insertions and deletions. Claim 2 was amended to depend from claim 1, rather than canceled claim 3, and to clarify "mono- or poly- hydroxy acid" by removing "or tannic acid". Claims 25 and 27 were amended to depend from claims 1 and 16, respectively, rather than canceled claim 24. As no new matter has been added, Applicant respectfully submits that all claims are in condition for allowance.

### **THE DOUBLE PATENTING REJECTION**

Claims 1, 2, 4-9, 11-23, and 25-30 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/501,218. As this is a provisional rejection, Applicants will address the rejection when either copending Application No. 09/501,218 or the present application is allowed.

### **THE REJECTIONS UNDER 35 U.S.C. § 103**

Claims 1, 2, 4-9, 11-23, and 25-30 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,891,440 to Lansky ("Lansky"), in view of U.S. Patent No. 5,985,300 to Crotty et al. ("Crotty") and U.S. Patent No. 6,071,543 to Thornfeldt et al. ("Thornfeldt") for the reasons set forth on pages 4-6 of the Office Action. Applicant respectfully traverses the rejection.

Lansky discloses an oral phytoestrogen supplement prepared from pomegranate material, *e.g.*, pomegranate seeds, and schizandra berries and Chinese asparagus root. *See e.g.*, Lansky, col. 2, lines 49-56. Lansky discloses an ointment prepared by pressing pomegranate seed to obtain oil and mixing the oil with coconut milk to form a mixture. *See e.g.*, Lansky, col. 3, lines 7-11. Lansky also discloses that the oral supplement or ointment may be administered to relieve various symptoms in menopausal women or postmenopausal women. *See e.g.*, Lansky, col. 3, lines 50-56. Lansky further discloses that the compositions of the invention can be used to create topical phytoestrogen supplements. *See, e.g.* Lansky, col. 3, lines 50-57.

Crotty discloses a cosmetic product that is an adhesive strip to remove keratotic plugs and to deliver active ingredients to the skin. *See, e.g.*, Crotty, col. 2, lines 40-42. Crotty also teaches that a wetting agent, preferably water, is needed for the delivery of active ingredients to the skin. *See, e.g.*, Crotty, col. 5, lines 65 to col. 6, line 11.

Thornfeldt teaches compositions containing either pyridine thiols, metal sulfides, or metal oxides and methods for preventing signs and symptoms of aging using the disclosed compositions. *See, e.g.*, Thornfeldt, col. 3, lines 42-47. These compositions are applied to the skin or mucous membranes. *See, e.g.*, Thornfeldt, col. 3, lines 47-50.

In the Office Action, it is alleged that the present invention is obvious over Lansky, in view of Crotty and Thornfeldt. Applicant respectfully submits that combination of Lansky with Crotty and Thornfeldt does not teach all of the elements of the claimed invention. For example, Lansky does not disclose or suggest the presence of a manganese, copper, or selenium component. Thus, Lansky does not disclose all of the elements of the claimed invention and in particular does not disclose the claimed oral composition.

Crotty does not remedy the shortcomings of Lansky. Crotty discloses adhesive strips that are applied to the skin. *See, e.g.*, Crotty, col. 2, lines 40-42. Crotty, similar to Lansky, does not disclose or suggest a composition containing a manganese, copper, or selenium component. Further, Crotty is directed to an adhesive strip and, accordingly, cannot be combined with the oral formulation of Lansky to disclose or suggest the oral compositions of claim 22. *See, e.g.*, Crotty, col. 2, lines 40-42. Clearly, an adhesive strip as disclosed in Crotty would not be combined with an oral formulations as disclosed in Lansky. Thus, the combination of Lansky and Crotty does not disclose all of the elements of the claimed invention.

Thornfeldt does not remedy the shortcomings of the combination of Lansky and Crotty. Thornfeldt discloses compositions containing metal ions complexed with pyridine-thiols or are metal sulfides or metal oxides that allegedly reverse the visible signs of aging. At best, the compositions of Thornfeldt can disclose a manganese, copper, or selenium component complexed with pyridine-thiols, or a sulfide or oxide of a manganese, copper, or selenium component. In contrast, the present claims recite a manganese component, *i.e.*, manganese ascorbate or a manganese ascorbate complex; a copper component, *i.e.*, copper sebacate; or a selenium component, *i.e.*, selenium complexed with an amino acid. *See, e.g.*, Specification, page 16, lines 5-11; 12-19; and 27-31. Further, Thornfeldt only discloses

applications to the skin or mucous membranes and, accordingly, cannot be combined with Lansky to disclose or suggest the oral compositions of claim 22. *See, e.g.,* Thornfeldt, col. 3, lines 47-50. Thus, the combination of Lansky with Crotty and Thornfeldt does not disclose all of the elements of the claimed invention and in particular does not disclose the claimed oral composition.

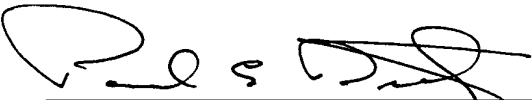
With regard to all claims not specifically mentioned, these are believed to be allowable not only in view of their dependency on their respective base claims and any intervening claims, but also for the totality of features recited therein.

All claims are believed to be in condition for allowance. Should the Examiner disagree, Applicant respectfully invites the Examiner to contact the undersigned attorneys for Applicant to arrange for an in-person interview in an effort to expedite the prosecution of this matter.

No fee is believed to be due for the amendments herein. Should any fee be required, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date: December 9, 2002

  
\_\_\_\_\_  
Paul E. Dietze (Reg. No. 45,627)  
For: Victor N. Balancia (Reg. No. 31,231)

**PENNIE & EDMONDS** LLP  
1667 K Street, N.W.  
Washington, DC 20006  
(202) 496-4400

Enclosure

**APPENDIX A**  
**MARKED UP VERSIONS OF THE AMENDED CLAIMS**

Application No.: 09/501,217; Filed: February 10, 2000

1. (Amended Thrice) A dermatological agent for managing a dermatological condition in a patient comprising:
  - at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals;
  - a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;
  - or hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;
  - a mono- or poly-hydroxy acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin;
  - [a cysteine component; and]
  - a manganese component; and
  - a pharmaceutically acceptable carrier.
4. (Amended) The dermatological agent of claim [3] 1, wherein the mono- or poly- hydroxy acid is selected from the group consisting of glycolic acid, lactic acid, citric acid, [tannic acid,] salicylic acid, and mixtures thereof.
25. (Amended) The dermatological agent of claim [24] 1, wherein the at least one fruit extract is selected from the group consisting of apricots, apples, pears, peaches, pineapples, papayas, pomegranates, cherries, kiwis, tangerines, grapes, oranges, and mixtures thereof.
27. (Amended) The dermatological agent of claim [24] 16, wherein the transition metal component comprises zinc.